K071761

AUG - 3 2007

Lloyd Linden INC.

No. 10-2, Nei-Chung-Fu, Kan-Chiao Village, Wanli, Taipei County, Taiwan
TEL: +886- 2-2492-5025 FAX: + 886-2-2492-3113

510(k) Summary

Device

Trade name: **LLOYD LINDEN EO4 power standup wheelchair**

Common name: **Standup wheelchair**

Classification name: **Standup wheelchair**

Medical specialty (Panel): **Physical Medicine Device**

Regulation number: **890.3900**

Product Code: **IPL**

Classification: **Class II**

Predicate devices

Lifestand LSC (K061726) / Lifestand

Intend use of device

LLOYD LINDEN EO4 power standup wheelchair is a product which changes people's position from sitting to standing and standing to sitting but also any position in between. It provides indoor and outdoor mobility.

Device description:

The **LLOYD LINDEN EO4** power standup wheelchair is an indoor/outdoor power stand up wheelchair that is battery operated. The design of this wheelchair is basically similar to other power stand up wheelchairs that are already on the market. It consists primarily of a welded steel frame, transaxle motor drive system, braking system and electronic motor controller and is powered by two **12 volt** DC batteries, and utilize a charger.

Substantial equivalence:

The **LLOYD LINDEN EO4 power standup wheelchair** is substantially equivalent to the **Lifestand LSC (K061726)** manufactured by **Lifestand.**

There are minor differences in performance specifications of the power standup wheelchairs, these differences do not alter the intended function and use of the device, nor do they raise any new questions pertaining to safety or effectiveness. Therefore, **LLOYD LINDEN INC.** believes that the **LLOYD LINDEN EO4** power standup wheelchair is substantially equivalent to legally marketed devices currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Lloyd Linden, Inc.
% Junnata Chang
No. 10-2, Nei-Chung-Fu
Kan-Chia Village
Wanli, Taipei County
Taiwan

AUG - 3 2007

Re: K071761
Trade/Device Name: Lloyd Linden E04 Power Standup Wheelchair
Regulation Number: 21 CFR 890.3900
Regulation Name: Standup wheelchair
Regulatory Class: Class II
Product Code: IPL
Dated: June 20, 2007
Received: June 29, 2007

Dear Junnata Chang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Device descriptive information

3.1 Statement of indication for use

Statement of Indications for Use

510(k) Number (if known): _____

Device Name: **LLOYD LINDEN EO4 power standup wheelchair**

Indications for Use:

The **LLOYD LINDEN EO4** power standup wheelchair is a product which changes people's position from sitting to standing and standing to sitting but also any position in between. It provides indoor and outdoor mobility.

Prescription Use _____ Over-The-Counter Use __X___

(Part 21 CFR 801 Subpart D) AND/OR (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE) Page 1 of 1

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K07761

(Posted November 13, 2003)